IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. AM100123)

In re Application of:	)	Appln. No.: 09/840,485
	)	Confirmation No.: 5730
ROCKY B. BIGBIE *et al.*	)	Customer No.: 25291
	)	Group Art Unit: 1645
Filed: 04/23/2001	)	Examiner: K. Shahnan-Shah
	)	
For: EQUINE PROTOZOAL MYELOENCEPHALITIS VACCINE	)	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AFTER FINAL REJECTION

Dear Sir:

To remove issues on appeal, please amend the above-referenced patent application according to the instructions in the below Appendix (incorporated herein by reference thereto) and consider the remarks in a favorable light.

REMARKS

Reconsideration of this application, as amended, is respectfully requested.

Claims 1, 2, 4-8 and 10-14 are pending in the subject application and stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph, due to an alleged deficiency in the written description regarding the deposit of the organism having ATCC Accession No. PTA-2972. Upon recent review of the file history in preparation for drafting the appeal brief, it has been determined that further response to the Examiner is warranted to remove this particular issue on appeal. Although Applicants appreciate that they cannot amend the finally rejected application as a matter of right, they think that the present amendment evidencing the proper deposit of the organism having ATCC Accession No. PTA-2972 pursuant to the Budapest Treaty is deemed necessary to simplify the issues on appeal.

Without comment as to the merits of the rejection, the amendment adds the complete name and full street address of the American Type Culture Collection depository to the specification. (It is noted for the Examiner's benefit that the date of deposit was already recited in the

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specification.) Additionally, it is averred that the *Sarcocystis neurona* isolate designated SNg, having ATCC Accession No. PTA-2972, has been deposited and accepted in the American Type Culture Collection under the provisions of the Budapest Treaty. It is also averred that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of the patent on this application.

Applicants respectfully ask that the Examiner kindly enter the proposed amendment, albeit after a final rejection, and withdraw the rejection of the pending claims insofar as the written description requirement is concerned. The present amendment does not present any new issues requiring further consideration or search and requires only a cursory review by the Examiner. The amendment introduces no new matter into the application. Applicants previously highlighted the fact that the starting material, *i.e.*, *S. neurona*, was available and identifiable at the time of filing the application and, as a consequence, they did not realize that any amendment would be necessary. Because the Examiner did not find the prior arguments persuasive, it is now seen on Applicants' reconsideration and fresh perspective of the issues that the addition of the deposit information into the specification and the appropriate affirmations in the record may remove the necessity of appeal on this particular issue.

Moreover, under the guidelines of M.P.E.P. § 714.13, any refusal to enter the proposed amendment should not be arbitrary. The proposed amendment should be given sufficient consideration to determine whether the issues on appeal are simplified or whether the claims are in condition for allowance. In sum, Applicants hope that the Examiner will enter the amendment and reconsider the rejections of record in a new, favorable light.

To further simplify the issues on appeal by eliminating one or more of the remaining rejections of record, or perhaps provide a response that places the application in condition for an immediate allowance, additional comments will be made in traversal of the outstanding rejections as follows:

(1) The Examiner has sustained the rejection of Claims 5-8 and 10-14 as being unpatentable under 35 U.S.C. § 112, first paragraph, because the specification allegedly fails to comply with the enablement requirement. In the Examiner's opinion, the rejection is justified because the art allegedly teaches no vaccine to protect horses from parasites and the specification allegedly does not provide substantive evidence that the claimed vaccine is capable of inducing

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protective immunity for prevention or amelioration of equine protozoal myeloencephalitis ("EPM"). In Applicants' previous response in the record, Applicants pointed out that the specification does demonstrate that the vaccine in fact induced immunogenicity and the results in Example 3 established that the antibody found by IFA in the horses' serum effected a pronounced reduction in the number of plaques of viable organisms - they were neutralized. Applicants also previously mentioned that the USDA accepted the IFA study as a basis of a conditional license to market the EPM vaccine.

For the benefit of the Examiner, it is explained that the USDA grants conditional licenses under expedited procedures before the full vaccination/challenge studies are completed to meet emergency conditions or when other special circumstances warrant urgent availability of the vaccine. However, conditionally licensed products must have a reasonable expectation of efficacy to be placed on the market (see http://epmvaccine.com/technical/06Regulatory.htm). Since the USDA has relied upon the data, the standard IFA screening protocols and results that are described in the instant specification clearly provide sufficient substantive evidence that the claimed vaccine is capable of inducing protective immunity for the prevention or amelioration of EPM.

Moreover, the Examiner's finding that the art teaches no vaccine to protect horses from parasites does not mean that the ordinary practitioner could not practice the claimed invention. In fact, Applicants' introduction of the first successful *S. neurona* vaccine on the market is real proof that the practitioner would be readily able to use the vaccine without the exercise of undue experimentation (see http://epmvaccine.com/technical/01fdvaccine.htm).

(2) The Examiner has held Claims 1, 2, 4-8 and 10-14 unpatentable under 35 U.S.C. § 112, second paragraph, because the Examiner considers certain terminology indefinite, that is, "capable" (Claim 1), "optionally" (Claim 5), "about 1% to 50%" (Claim 10), "about 5% to 20%" (Claim 11), "sufficient quantity" (Claims 4 and 6), "amount sufficient" (Claims 8 and 9) and "an effective immunizing amount" (Claim 5). In the previous response of record, Applicants have traversed this rejection on the grounds that the language would be clear to those skilled in the art.

There is no question that one of ordinary skill in the art would understand each of the terms within the context of the claim language and the teachings of the specification. Additionally, most, if not all, of these terms have become art-recognized and are often used in claims of many issued patents. See, for example, "capable of inducing IgG antibodies" in U.S. Patent No. 4,387,091;

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"optionally other ingredients" in U.S. Patent No. 4,386,979; "containing about 6.0 to 7.0% solids" in U.S. Patent No. 3,851,082; "vaccine contains sufficient live attenuated Salmonella bacteria to elicit an immune response" in U.S. Patent No. 6,764,687; "in an amount sufficient to provide a passive immunization" in U.S. Patent No. 6,299,879; "vaccine comprising ... an effective immunizing amount of a mutant herpesvirus" in U.S. Patent No. 6,541,009, among illustrations in numerous other patents.

(3) The Examiner has sustained the rejection of Claims 1, 2 and 4 as unpatentable under 35 U.S.C. § 102(b) as being anticipated by Granstrom *et al.* The Examiner believes that Granstrom *et al.* teach the claimed immunogenic composition. With all due respect, this is not true. The reference merely teaches antigens of cultured *S. neurona* merozoites. There is absolutely no description of Applicants' specific composition.

One critical element of the recited immunogenic composition in the claims is the **inactivated** *Sarcocystis neurona* cells. Granstrom *et al.* fail to anticipate the claimed invention for the plain and simple reason that there is no identity of invention. The authors do not disclose any inactivated products, only a cell culture. Inactivated *Sarcocystis neurona* cells and cultured *Sarcocystis neurona* merozoites are definitely not the same thing.

Physically speaking, the live, cellular composition of Granstrom *et al.* is not the same entity as Applicants' inactivated composition. In fact, the inactivated characteristic of the *S. neurona* cells of the present invention is neither inherent nor easy to obtain from the cultured *S. neurona* merozoites taught in the art. It is well known in the art that protozoa are very resistant to conventional disinfectants and inactivation is a slow process. Take, for example, the method of inactivation illustrated in the specification wherein the merozoite harvests are inactivated by a formalin solution over a period of no less than 48 hours (see the top sentence on page 14 of the application). Without any doubt, it is quite clear that Granstrom *et al.* do not describe the present invention. Since there is no basis in fact, the Examiner may wish to reconsider and withdraw this rejection.

In sum, the Examiner may find that this response *on its face* places the application in a condition for allowance. Applicants would be grateful for the Notice of Allowance. Otherwise, at the very least, this response will reduce the issues on appeal.

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Accordingly, favorable treatment is respectfully urged.

Respectfully submitted,

WYETH

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